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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,191

09/11/2007

Yusuke Sakai

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8791

7590

08/03/2010

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EXAMINER

HOLLOMAN, NANNETTE

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,191	<b>Applicant(s)</b> SAKAI ET AL.	
	<b>Examiner</b> NANNETTE HOLLOMAN	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Applicants' arguments, filed March 3, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Claim Rejections - 35 USC § 102***

Claims 1, 4, 6, 8 and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Bowman et al. (US Patent No. 5,767,153). This rejection is maintained.

### **Applicant's Arguments**

Applicant argues Bowman describes PGFs as an example of oily medicaments, however, does not specifically disclose PGFs selected from at least one of latanoprost, isopropyl unoprostone, travoprost and bimatoprost as recited in claim 1. Applicant's arguments have been fully considered but they are not persuasive.

### **Examiner's Response**

Bowman et al. disclose, as previously asserted, in TABLE 1 a prostaglandin  $F_{2\alpha}$  derivative,  $PGF_{2\alpha}$ -1-Isopropyl Ester, which is a synonym for Bimatoprost as disclosed by the disclosed Material Safety Data Sheet. Therefore, Bowman et al. encompass the limitation of the claims.

### ***Claim Rejections - 35 USC § 103***

Claims 2, 3 and 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. (US Patent No. 5,767,153) as applied to claims 1, 4, 6, 8 and 9 above, and further in view of Hellberg et al. (US Patent No. 6,342,524). This rejection is maintained and further applied to claim 10. Claim 2 is cancelled.

### **Applicant's Arguments**

See Applicant's arguments supra in regard to Bowman et al. Applicant further argues Bowman is silent about the stability of the PGFs in the emulsion. Applicant also argues one of ordinary skill in the art would not understand to modify Bowman to include a PGF such as latanoprost in view of the teaching of Hellberg, since PGFs such as latanoprost typically have poor solubility and are chemically unstable when combined with an aqueous solution. Applicant argues Hellberg while disclosing latanoprost and travoprost, fails to disclose an oil-in-water emulsion and is silent about medium chain fatty acid triglycerides, which maintain the stability of the PGF in the emulsion. Applicant further argues since one of ordinary skill in the art would understand the claimed PGFs to be incompatible with an oil-in-water emulsion and the references do

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not teach otherwise, one would not modify Bowman in view of Hellberg to arrive at the claimed combination of elements. Applicant further argues unexpected results.

Applicant's arguments have been fully considered but they are not persuasive.

### **Examiner's Response**

See Examiner's response supra in regard to Bowman et al. In regard to the stability of the PGFs in the emulsion, the limitation is not recited in the claims. In regard to modifying Bowman to include a PGF such as latanoprost, Bowman et al. disclose that any prostaglandins and their derivatives and conjugates may be used (column 4, line 67 to column 5, line 2) and further discloses when poorly water soluble medicaments are dissolved in oil, their bioavailability to the targeted tissue may be enhanced (column 5, lines 24-27), thus, overcoming the solubility issues in an aqueous solution. Bowman also discloses the medium chain fatty acid triglycerides. Hellberg was disclosed to teach that latanoprost and travoprost are the most preferred prostaglandin, therefore, providing the motivation to use latanoprost as the prostaglandin in the oil-in-water emulsion of Bowman.

In regard to the alleged unexpected results, wherein it was recognized that an oil-in-water emulsion formulating latanoprost together with a medium chain fatty acid triglyceride and a water-soluble polymer suppressed the degradation of latanoprost, this does not appear to be unexpected, since the emulsion of the art encompasses the claimed limitations. Additionally, it appears the results would be expected, since prostaglandins are known to be hydrolytically unstable as taught by Schneider (US

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Patent No. 5,631,287), therefore one would have expected the stability of the prostaglandin to increase in the oil-water vehicle of Bowman in view of Hellberg.

Furthermore, the comparison does not appear to be proper, since the closest prior art, Bowman, discloses an oil-in-water emulsion comprising a prostaglandin, while Applicant has compared and emulsion to a water based vehicle.

Even, assuming, purely *arguendo*, that unexpected results had been shown, Applicant's claims encompass more compounds, i.e. prostaglandin derivatives than disclosed by Table 2 in the specification, therefore the examples are not commensurate in scope with the instant claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 800am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H./

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612